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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,774	10/09/2001	H. Paul Redmond	1194-180	3168
6449	7590	04/06/2004	EXAMINER MAIER, LEIGH C	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p>09/971,774</p>	<p><b>Applicant(s)</b></p> <p>REDMOND ET AL.</p>	
	<p><b>Examiner</b></p> <p>Leigh C. Maier</p>	<p><b>Art Unit</b></p> <p>1623</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-12 and 26 are pending.

### ***Claim Rejections - 35 U.S.C. § 103***

Claims 1-5, 8, 9, 11, and 12 are again rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743), as set forth in the previous Office action.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of ALLGOOD et al (US 5,176,651).

Claims 1-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of NICOLSON et al (US 5,262,403).

Claims 1-5, 8, 9, 11, 12, and 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over JACOBI et al (Langenbecks Arch. Chir., 1997) in view of MONSON et al (WO 92/00743) and further in view of PHYSICIANS' DESK REFERENCE (PDR - 1995).

The invention is as set forth in the previous Office action. Applicant's arguments filed December 24, 2003 have been fully considered but they are not persuasive. The arguments will be addressed as a group, as Applicant has not argued them separately.

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Applicant first contends that JACOBI does not teach each and every step of the present claims. As the rejection is one of obviousness, this was clearly stated in the previous Office action.

With regard to the combination of JACOBI and MONSON, Applicant alleges hindsight reasoning by the examiner. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The reasoning is repeated below.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam (with or without heparin) during laparoscopic cancer surgery, as JACOBI had taught that the intraperitoneal administration of taurolidine or a combination of taurolidine and heparin at the time of laparoscopic surgery for tumor removal reduces the incidence of tumor growth and trocar metastases. MONSON had taught that these species (taurolidine and/or taurultam) are functional equivalents for the inhibition of metastases. In the absence of unexpected results, one of ordinary skill would reasonably expect success in the use of taurolidine and/or taurultam for this art-disclosed utility. It would be within the scope of the artisan to optimize the solution concentration with routine experimentation. With regard to the use of a trocar, the reference is drawn to the *decreased incidence of trocar metastases*, so the use of this instrument is clearly implied.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a solution of taurolidine and/or taurultam before and/or after cancer surgery for the benefits of treating malignancies as well as prevention of metastases, taught by MONSON. In the absence of unexpected results, it would be further obvious to use this procedure for all of the recited cancers with a reasonable expectation of success. It would be within the scope of the artisan to select any common type of administration, such as IV or catheter, to administer the solution.

In addressing the other references, Applicant appears to be arguing that the references are merely general discussions of broad topics, whereas each reference was cited for very specific teachings that allowed their combination with JACOBI and MONSON.

Applicant further contends that none of the references can be combined with JACOBI and MONSON to suggest the instant invention. However, Applicant neglects to provide any reasoning as to why the combinations are deficient.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Examiner's hours, phone & fax numbers***

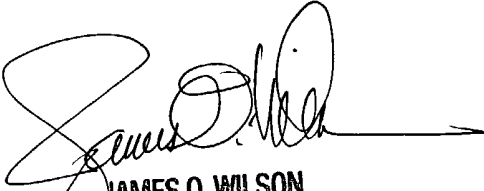
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier  
Patent Examiner  
March 26, 2004



**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**